Effectiveness of Individualised Medical Nutrition Therapy in Managing Gestational Diabetes Mellitus

SHORT SYNOPSIS

Submitted in partial fulfillment of the requirement of the degree of

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by

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Certificate

I hereby declare that the Short Synopsis titled "Effectiveness of Individualised Medical Nutrition Therapy in Managing Gestational Diabetes Mellitus" being submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy in Department of Nutrition and Dietetics under School of Allied Health Sciences of Manav Rachna International Institute of Research & Studies, Faridabad during the academic year 2024-25 is a bona fide record of original work carried out under the supervision of Dr. Gurjeet Kaur Chawla and Dr. Renu Gupta. This work has not been submitted to any other university or institute, in part or in full, for a degree or diploma program. Further, it is certified that this Short Synopsis is free from plagiarism and proof of the same has been submitted.

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Abstract

Gestational diabetes mellitus (GDM) is a condition of glucose intolerance that develops for the first time in pregnancy without any previous history of diabetes. Although the cases of GDM have increased all over the globe, India has a higher incidence of GDM as compared to the western countries. Undiagnosed and untreated in pregnancy, GDM can not only result in maternal and fetal complications but also a greater threat of developing Type 2 Diabetes Mellitus in the mother and child later in life. Medical Nutrition Therapy (MNT) is the first approach to control hyperglycemia and to ensure adequate weight gain for the mother as well as the growth of the fetus. Dietary counselling, physical activity and self-monitoring of sugar levels form the basis of MNT. For MNT to be effective, dietary advice, and counseling must be done in an easy-to-comprehend manner, tailored to individual needs and lifestyles.

This investigation evaluates the baseline dietary consumption & food habits of ninety newly diagnosed GDM patients in the Delhi geographical area, ranging between 18 and 45 years of age. The assessment forms the basis of personalized dietary counselling, which includes healthy food choices, cooking methods & practical ways to follow a healthy eating pattern tailored to the individual's specific needs. A continuous follow-up will be done till delivery to see the effect on sugar levels and evaluate the need for pharmacological intervention. Gestational weight gain as well as fetal outcomes in terms of birth weight and neonatal measurements such as head circumference and length will be recorded. The dietary information will be gathered through an interviewer-administered dietary recall method. We aim to perform statistical analysis to assess the effectiveness of the nutrition therapy in achieving glycaemic control, gestational weight gain, and fetal outcome. The results will be explained in a comprehensible fashion.

Keywords

Delhi, Dietary, Gestational Diabetes Mellitus, Medical Nutrition Therapy, Personalised

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1. Description of Broad Area

Motherhood is the most significant responsibility assumed by humankind in the course of a lifetime. A growing fetus is entirely dependent upon the body of its mother to fulfil all of its requirements. Therefore, expecting mothers must ensure that they are healthy and well-nourished throughout the course of their pregnancy. Many physiological, anatomical, & metabolic adjustments begin shortly after conception & continue through the duration of a pregnancy. The majority of these changes are a reaction to the physiological impulses produced by the fetus and the placenta (Kampmann et al., 2019).

1.1 Pathophysiology of Gestational Diabetes Mellitus

GDM is characterized by glucose intolerance of any degree or elevated blood glucose levels, both of which are identified initially throughout pregnancy. Data collected from around the world shows that, on average, gestational diabetes affects approximately 7% of pregnancies worldwide (MacGregor et al., 2020). In comparison to women from other geographical areas, Asian women have a greater risk of getting GDM, even though their BMI is within the acceptable range.

The hyperglycemia-hyperinsulinemia theory, often known as the Pedersen hypothesis, is typically attributed to Jorgen Pedersen, despite its first formulation in the 1920s (Catalano PM et al., 2011). According to Pedersen, fetal hyperglycemia from maternal hyperglycemia causes fetal islet tissue to hypertrophy and causes insulin hypersecretion. This translates to an increase in fetal glucose use. This phenomenon explains the reason behind newborn's aberrant structures and alterations. The Pedersen hypothesis is the most linked explanation behind fetal expansion or macrosomia.

GDM often arises from beta-cell malfunction along with chronic insulin resistance (IR) during the course of pregnancy. Consequently, the contributing factors in the pathogenesis of GDM are beta-cell impairment coupled with tissue insulin resistance. In the majority of instances, these deficits are pre-existing and have the potential to worsen, hence indicating an elevated susceptibility to developing Type 2 Diabetes Mellitus during pregnancy (Plows et al., 2018).

The primary function of beta cells is to store and release insulin in response to an elevation of blood glucose levels. Beta-cell dysfunction is characterized by the loss of beta cells' capacity to accurately detect blood glucose levels and secrete an appropriate amount of insulin in response. Malfunctioning beta-cells may arise due to prolonged and excessive insulin secretion. Such secretion is a reaction to a chronic surplus of fuel. Nevertheless, there is a wide range of variation and complexity in the precise pathways that cause beta cell dysfunction.

Plows et al. (2018) illustrated that malfunctioning of beta cells is further increased due to insulin resistance. Insulin resistance is a reduced response of cells to insulin. The decreased response happens primarily because of the hormonal secretion by the placenta during the second trimester of pregnancy. Cortisol, placental lactogen, and estrogen resist the action of insulin and help sustain the pregnancy by ensuring an adequate supply of glucose to the fetus. This effect, also called the “counter insulin” effect, is usually noticed between the 20th and the 24th weeks of pregnancy and continues until the 35th week when placental growth stops. The investigations conducted by Palani et al. (2014) showed that reduced insulin sensitivity increased the development of hyperglycemia in the mother. This further strains beta-cells to produce more insulin in response to elevated blood glucose levels. This excess load drives beta-cell failure, thus starting a vicious cycle of elevated blood glucose levels, reduced insulin sensitivity, and further beta cell dysfunction.

Figure 1 presents a schematic representation of the interplay of beta-cell dysfunction and insulin resistance in GDM and in normal pregnancy.

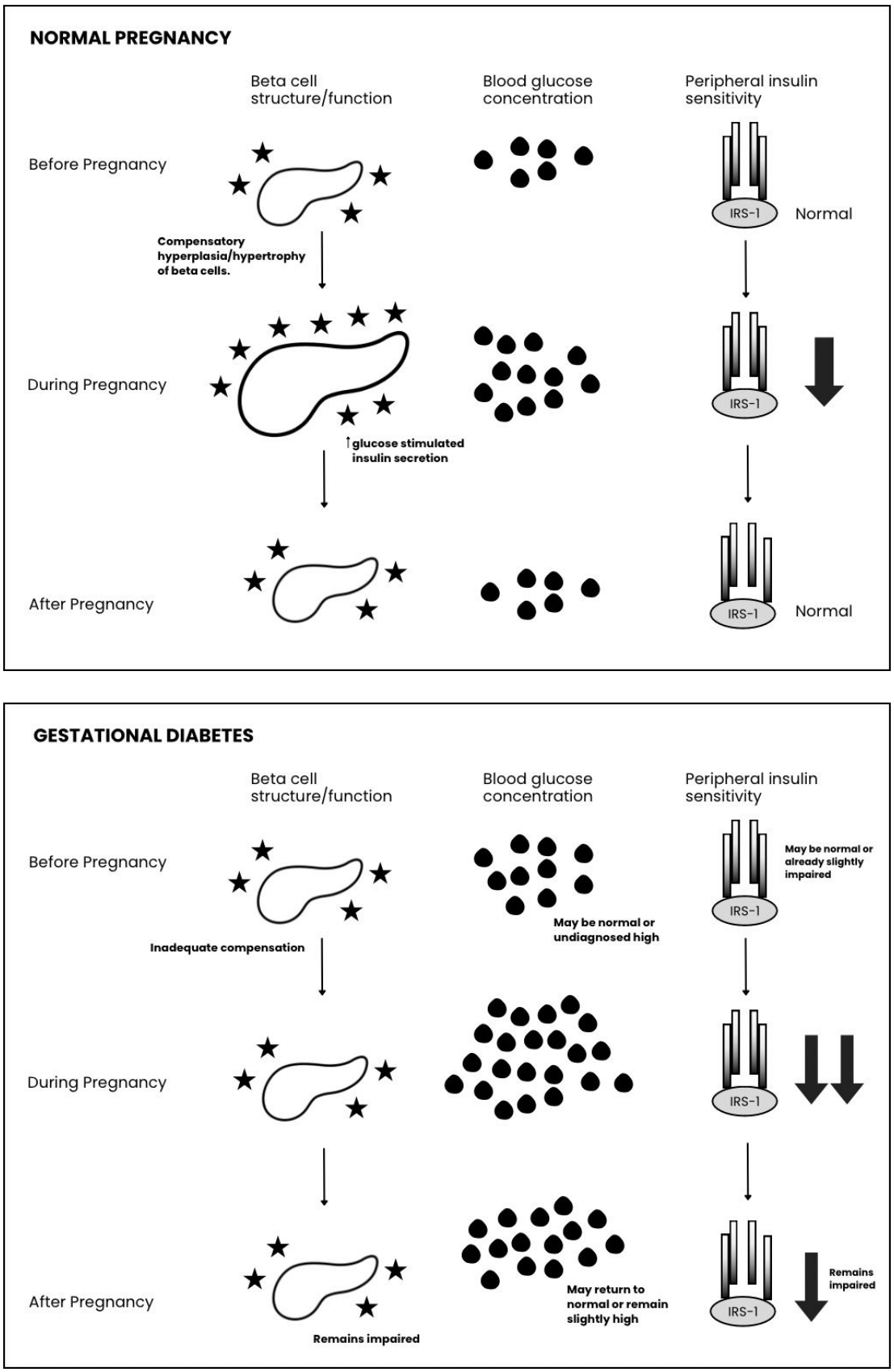

Figure 1 Beta-cell dysfunction along with insulin resistance in normal pregnancy and GDM (Plows et al., 2018).

As the metabolic needs increase in a normoglycemic pregnancy, beta cells undergo both hyperplasia and hypertrophy as an adaptive mechanism. As the insulin sensitivity decreases, the blood glucose levels rise. After the baby is delivered, beta-cells, blood glucose levels, and insulin sensitivity return to their normal states. However, in gestational diabetes, beta-cells fail to meet the increased metabolic demands of pregnancy. This failure of beta-cells, coupled with reduced insulin sensitivity, causes hyperglycemia. After the pregnancy is over, beta cells, insulin sensitivity, and blood sugar levels can either normalise or remain compromised. Compromised levels can cause GDM in subsequent pregnancies or even T2DM.

1.2 GDM in the Indian Context

GDM is a significant and escalating concern in many regions around the globe. The worldwide occurrence of GDM ranges from 2% to 6% and has the potential to reach as high as 20% among populations at elevated risk (Ferrara A, 2007). There is a dearth of precise data about the prevalence of GDM because of the absence of internationally acknowledged and implemented diagnostic criteria and screening methodologies (Kendrick JM, 2011). However, it is believed that around 10% of pregnant women globally are affected by GDM (Veeraswamy et al., 2012). Ferrara A (2007) further pointed out that an increase in the prevalence of GDM coincides with the rise of obesity and T2DM cases globally.

Green et al. (2012) illustrated that the prevalence rates of GDM in the US may vary from 1% to 14%. However, this variation is owing to the diagnostic criteria adopted and the number of pregnant women studied. Seshiah et al. (2009) said that 90% of all the cases wherein the pregnant woman suffered from hyperglycemia could be attributed to GDM.

Incidence of GDM in India varies from 3.8% to 21%. The variations in incidence of GDM are due to certain factors such as geographic distribution of population and criteria adopted for diagnosis. Agarwal & Gupta (1982) found the incidence of GDM in urban areas to be on a higher side than that of the rural population. The incidence of GDM has increased substantially from 2% in 1982 to 7.62% in 1991, as observed by Narendra et al. (1991). The prevalence rate of 16.55% for GDM has also been observed in a large-scale survey conducted all over the Indian population in 2002

(Seshiah V et al., 2004). The incidence of GDM varies from 3.8% to 17.9%, which is substantially high as that of the western population. (Mishra et al., 2018).

The prevalence rates of GDM vary from 2.4% to 21% of all births. This variation is dependent on the geographic area of the research and the criteria of diagnosis used. The exact prevalence rates of GDM in India are not easy to estimate owing to differences in living conditions, socioeconomic conditions, and eating habits of different people (Punnose et al., 2023).

Women in India with GDM Strategy (WINGS), a project initiated by Indian Diabetes Federation (IDF), conducted a study from January 2013 to December 2014 at prenatal rural health clinics situated at Chennai and Tamil Nadu. The findings highlighted that there were similar prevalence rates of GDM observed between rural and urban parts of South India.

The result implies that the prevalence of GDM is also increasing in rural South India. This result emphasised the need for universal screening for all women, even if they do not exhibit any symptoms (Bhavadharini B. et al., 2016). Mothers with a history of GDM and subsequently their children are more likely to acquire T2DM later in life. Therefore, this demographic requires special attention, especially in developing nations.

1.3 Risks of GDM

Since GDM has varied short-term and long-term consequences for both the mother and the child, it is important to understand and efficiently treat or prevent GDM.

Having a diagnosis of GDM puts a woman at a ten times elevated risk of having T2DM within 5-10 years of giving birth; this risk is exacerbated by being overweight or obese. GDM may be responsible for the rising incidence of T2DM, which has occurred concurrently with a rise in obesity rates across the country. A few unfavorable pregnancy effects of GDM include macrosomia or large-for-gestational-age (LGA) babies, neonatal hypoglycemia, hyperbilirubinemia, birth traumas, shoulder dystocia, high likelihood of cesarean delivery, preterm delivery, and T2DM in the future. When hyperglycemia occurs throughout pregnancy and is not treated, it can lead to an increase in insulin production, which in turn can cause the fetus to grow at an abnormally rapid rate. The vast majority of instances are treatable with changes to diet and increased levels of physical exercise. Nevertheless, a few women will

require insulin therapy or oral hypoglycaemic medications to attain optimal glycaemic control (Anand et al., 2017).

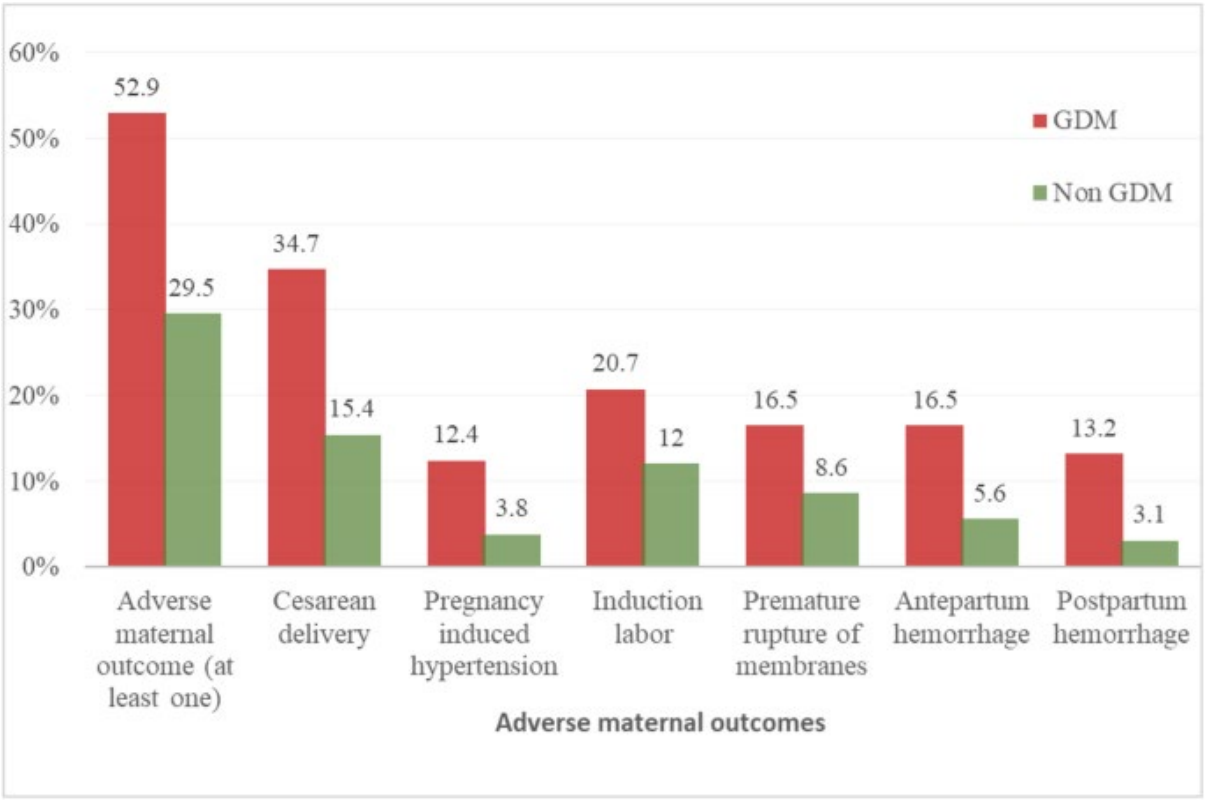

Figure 2: Adverse maternal outcomes reported by Muche et al., (2020)

GDM subjects have higher incidence rates of preeclampsia, approximately between 10 - 30%, in comparison to those with typical glucose tolerance, whose risk of developing preeclampsia ranges from 5 to 7%. Numerous research studies have established a correlation between preeclampsia and insulin resistance (Yang & Wu, 2022). People who experience preeclampsia before 34 weeks are more likely to have a premature birth. One percent of pregnancies result in polyhydramnios, which is an overabundance of amniotic fluid around the fetus. It is more commonly observed in people who are already at greater risk, such as women with diabetes. 1.5% to 66% of diabetic pregnancies exhibit polyhydramnios. This condition is usually connected with diabetic pregnancies.

Fetal overgrowth or macrosomia is the primary result of GDM. Macrosomia can subsequently lead to further complications including shoulder dystocia, infant hypoglycemia as well as impaired glucose tolerance in early youth and adolescence (Song et al., 2022). The hypothesis put out by researchers is that the exposure of a

fetus to the intrauterine surroundings of a woman with GDM leads to an elevated transit of glucose, amino acids, and fatty acids through the placenta. This in turn causes the fetus to produce more insulin and Insulin-like Growth Factor 1 at a higher level. When combined, they can cause fetal overgrowth, which is characterized by an increase in the body's ability to accumulate protein and fat. Macrosomia is recognized as a risk contributor to the incidence of shoulder dystocia, a type of obstructed birth.

For this reason, babies from such pregnancies involving GDM usually give birth through cesarean sections. Following child birth, issues such as hypoglycemia, hypocalcemia, hyperbilirubinemia, polycythemia, and birth trauma may arise. Children from GDM pregnancies face an elevated risk of having issues related to obesity, type 2 diabetes mellitus, cardiovascular disorders, and other metabolic disorders. Children of women going through Gestational Diabetes Mellitus (GDM) face almost twice the risk of experiencing childhood obesity from those not exposed to diabetic pregnancies. Such risks are intact regardless of any established potential variables such as body mass index (BMI) of the mother. Impaired insulin tolerance is determined in children at five years of age. For this reason, female child born from a GDM pregnancy face an elevated risk of developing GDM during their own lifespan, hence starting an abnormal GDM cycle from one generation to the next (Plows et al., 2018).

Additionally, research shows that after a diagnosis of GDM, gestational weight gain (GWG) outside of the Institute of Medicine's recommended criteria can raise the risk of GDM-related perinatal outcomes by 36–83%. New guidelines issued by IOM in 2009 established a weekly GWG rate for the second and third trimesters of pregnancy.

1.3.1 Effects of Increased BMI in Gestational Diabetes

For several years, BMI has been considered a risk factor for the development of GDM. Women who have a higher BMI before conceiving have a greater risk of developing gestational diabetes. The chance of developing gestational diabetes rises by 4% for every point that is added to a woman's BMI. This is because an excessive amount of body fat can lead to insulin resistance (IR). IR occurs when the cells in the body become less receptive to insulin. This means that more insulin is required to maintain normal blood sugar levels. Sharma et al. (2019) found that the incidence of GDM was at a maximum (36.6 %) in patients who had a BMI ranging from 31 to 35.

This emphasises the need for planning pregnancy at a suitable weight to alleviate metabolic changes and delivery issues which can be detrimental for both maternal and fetal health.

1.4 Diagnosis of GDM

The latest guidelines from the Ministry of Health and Family Welfare advise two screenings for GDM during routine prenatal care. The first testing should be done at the initial antenatal visit, ideally in the early stages of pregnancy. If the first test gives a negative result, it is advised to administer the second testing between the 24th and 28th weeks of pregnancy. It is important to ensure the conduction of a second test, as a considerable number of women develop blood sugar intolerance during 24-28 weeks of pregnancy. Furthermore, it is of note that only a third of women who happen to test GDM-positive are identified within the first trimester. If a pregnant individual presents beyond the 28-week gestational milestone, it is recommended that just a single test be conducted at that time.

Oral Glucose Tolerance Test Method

The experimental procedure involves the use of a single-step testing method, whereby a dose of 75 grams of oral glucose is administered and the subsequent measurement of blood sugar levels is conducted two hours after consumption. A dose of 75 grams of glucose ought to be administered orally, after dissolution in roughly 300 milliliters of water, regardless of whether women who happen to be pregnant are in a fasting or non-fasting condition, and regardless of their most recent meal. The solution must be consumed within a time frame of 5 to 10 minutes. Two hours after the administration of an oral glucose load, a plasma standardized glucometer assessment of blood glucose levels is recommended. The diagnostic criterion for GDM is the presence of a blood sugar level equal to or above 140 mg/dL. (Diagnosis & Management of GDM: Technical Guidelines, Ministry of Health & Family Welfare Govt. Of India, 2018)

1.5 Management of GDM

Guiding Principles

Pregnant women who get a positive diagnosis for GDM for the first time are recommended to start a treatment plan consisting of MNT along with physical activity

for two weeks. It is recommended that women participate in 30 minutes of moderate-intensity aerobic movement each day. This should be for no fewer than 5 days each week or a total of no less than 150 minutes each week.

1. After providing MNT for 2 weeks along with physical exercise, 2 hrs postprandial blood sugar (PPBS) needs to be checked.
2. A PPBS level of more than 120 mg/dL requires initiation of medical therapy according to established standards, which could be the use of metformin or insulin therapy.

1.6 Nutrition Therapy for GDM

Nutrition therapy is an essential subcategory of healthcare that focuses on diet, physical activity, and nutrition to diagnose, treat, and prevent various medical conditions. Nutrition therapy is widely prescribed along with medical therapy by a physician to treat different health conditions such as heart disease, diabetes, food allergies and sensitivities, obesity, and gastrointestinal ailments. Nutrition therapy services are usually provided by a qualified dietitian or a nutritionist. They collaborate with individuals to develop an individualized nutrition strategy that caters to the specific requirements of their health objectives. This strategy may involve adjusting the kinds of foods eaten, the amounts that are consumed, as well as providing direction regarding the planning and preparation of meals.

Nutrition therapy remains the standard first-line treatment for GDM. It entails carbohydrate-controlled individualized meal plans and educating people about the foods they should consume, as well as the foods that they should avoid. Appropriate nutrition during pregnancy can help meet the fetus's, the placenta's, and the mother's metabolic demands. It can also be a crucial first step toward a lifetime of nutritious eating. Therefore, nutritional therapy for GDM patients may be seen as a preventative measure against the generational transmission of obesity and diabetes.

Guiding Principles of MNT

1. Sufficient calorie intake to support optimal gestational weight gain.
2. Normoglycemia’s achievement along with maintenance. The following glycemic targets are advised for expectant mothers with GDM:
    i. plasma glucose level after fasting is less than 95 mg/dl (5.3 mmol/l)

ii. plasma glucose 1-hour postprandial is less than 140 mg/dl (7.8 mmol/l)
iii. plasma glucose 2-hour postprandial is less than 120 mg/dl (6.7 mmol/l)

3. Individualized nutrition assessment for an accurate appraisal of weight, height, current dietary intake, food preferences, cultural practices, and activity levels.
4. Determination of body mass index and the ideal range for weight increase during pregnancy.
5. The significance of self-checking blood sugar levels and keeping a note of all the readings, which are to be discussed in follow-ups.
6. Severe calorie restriction is never endorsed as it could cause ketonemia & ketonuria, along with affecting the development of the child.

1.6.1 Calorie Intake

There is limited specific data about the necessary calorie intake and the ideal weight gain for pregnant women with GDM. The Institute of Medicine (IOM) recommendation is used worldwide. It serves as the predominant reference for determining the recommended weight increase throughout each trimester of pregnancy, taking into account the individual's pre-pregnancy body mass index (BMI). However, the IOM guideline omits women with GDM. It also does not endorse weight loss during pregnancy. The IOM recommendations for gestational weight gain are as follows (IOM Pregnancy Weight Guidelines, 2009)**:**

Table 1 IOM Pregnancy Weight Guidelines (2009)

BMI (kg/meter sq)	Category	Total weight gain (kgs)	Total weight gain (LBS)	Rate of weight gain per week in 2nd and 3rd trimester (kgs/week) (mean)	Rate of weight gain per week in 2nd and 3rd trimester (LBS/week) (mean)
<18.5	Underweight	12.5-18	28-40	0.44-0.58 (0.51)	1-1.3
18.5-24.9	Normal	11.5-16	25-35	0.35-0.50 (0.42)	0.8-1
25-29.9	Overweight	7-11.5	15-25	0.23-0.33 (0.28)	0.5-0.7
>30	Obese	5-9	11-20	0.17-0.27 (0.22)	0.4-0.6

Various organizations like the American Diabetes Association (ADA) and the Academy of Nutrition & Dietetics (AND) agree that women should gain weight

according to IOM guidelines. Regarding obese or overweight women, moderate caloric restriction (approx. 30% of pre-pregnancy calorie intake and no lower than 1600 kcal per day) is recommended. During pregnancy, weight reduction is not recommended by any authoritative sources. Instead, it is advised to focus on slowing down weight increase to prevent maternal ketosis and mitigate any adverse effects on the mother or the fetus. (Blumer et al., 2013)

1.6.2 Carbohydrate Intake

Carbohydrates are the most essential macronutrient for women who have GDM. Increased blood glucose levels and postprandial hyperglycemia are caused, respectively, by the digestion and absorption of carbohydrates. Both the total amount of carbohydrates and the kind of carbohydrates consumed will have an effect on blood glucose levels. Therefore, hyperglycemia can be caused by a meal that contains a large quantity of carbohydrates (Zhang et al., 2023).

The idea of carbohydrate restriction for GDM predates the insulin era. There are a number of disagreements over the appropriate quantity and kind of carbohydrates for fetal growth and metabolism because glucose is the primary energy substrate for both the placenta and the fetus. No international consensus has been reached on the daily amount of carbohydrates that should be consumed by women who have GDM. The lower range of recommended carbohydrate intake is 35% to 40% of the total caloric intake. In the higher range, 50% to 60% of the total caloric intake may be from carbohydrates. However, various bodies seem to agree on not limiting carbohydrate intake below 175g per day. Most guidelines recommend the distribution of carbohydrates into three main meals and three small snacks to reduce high glycemic excursions post-meal.

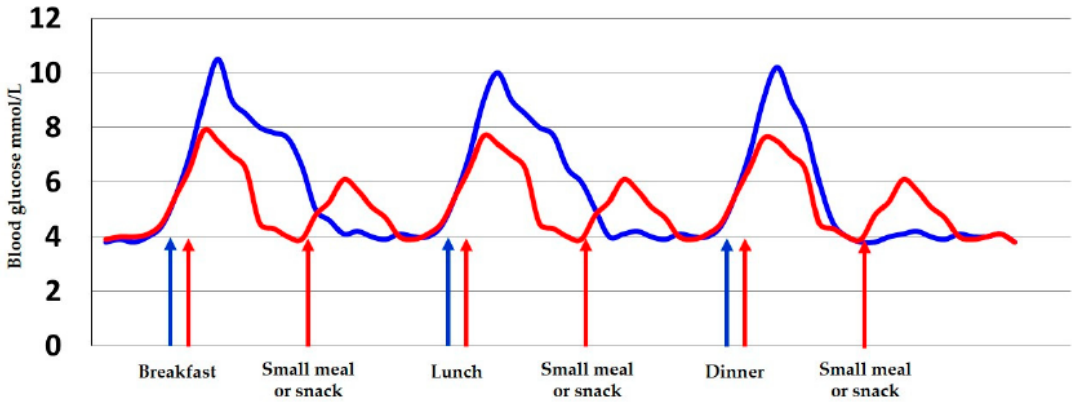

Figure 3: Blood glucose levels reports for different meal patterns by Rasmussen et al. (2020). The Blue curve shows a typical meal pattern (three meals), whereas the red curve illustrates a GDM meal pattern (three main meals and three snacks).

The majority of carbohydrate intake should be in the form of starchy foods that have a low glycemic index and are naturally high in dietary fiber. Some examples of such foods include vegetables, legumes, fruits, and whole grains. According to the American Diabetes Association (ADA), women with GDM should consume at least 28 g of fiber. These recommendations are comparable to those made by the IOM for women who are normoglycemic when they are pregnant. One strategy to achieve these targets is to consume 600g of fruit and vegetables every day. At least 300g of this portion should be vegetables, with a focus on fibrous and rough vegetables. One can also choose wholemeal rice, pasta, and bread. Carbohydrates that can be absorbed quickly & have a glycemic index (GI) greater than 70 are classified as high-GI dietary items, whereas carbs that can be absorbed more slowly with a glycemic index that is equal to or less than 55 are classified as low-GI foods. In T2DM, which has a similar pathophysiology to GDM, eating a low glycemic load diet has been shown to enhance glycemic control.

Table 2: Nutrition Dietary recommendations reported by Rasmussen et al. (2020)

Dietary Components	Recommendations
Energy	Excessive weight gain should be avoided and a calorie restriction of 30–33% is advisable in women with overweight or women who have already gained the recommended weight during pregnancy
Carbohydrates	Exact amount of carbohydrate should be individualized. A minimum of 175 g/d should be ensured. Patients should be guided to choose starchy foods such as vegetables, legumes, fruits, and whole grains.Carbohydrate intake should be distributed throughout the day.
Protein	Total amount of protein should be 10–35E% with a minimum of 71 g/d. Protein intake should primarily come from plants, lean meat, and fish.
Fat	Total amount of fat should be 20–40E% with a maximum of 10E% from saturated fat, a minimum of 10–20E% from MUFAs, and 5–10E% from PUFAs. An intake of a minimum 350 g of fish/week may be advisable.
Folic acid	500–600 µg/d is recommended. Daily supplement of 400 µg/d may be advisable for all women at childbearing age and during the first 12 week of gestation.
25-Hydroxyvitamin D	5–10 µg/d is recommended depending on how much sunlight the woman gets.
Calcium	900–1000 mg/d is recommended. Supplement may be advisable in women with a lack of intake of dairy products.
Iron	27–40 mg/d is recommended.
Probiotics	It remains unresolved whether probiotics have beneficial metabolic effects in women with GDM.

d, daily; E%, energy precent; GDM, gestational diabetes mellitus; MUFAs, monounsaturated fatty acids; PUFAs, polyunsaturated fatty acids.

1.6.3 Protein Intake

Consumption of an adequate amount of protein throughout pregnancy is necessary to satisfy the requirements of the developing fetus and prevent the depletion of maternal reserves as well as breakdown of muscle tissue. Most dietary standards suggest that individuals should consume 20% of their daily energy intake from protein, which is between 60 and 80 grams of protein daily. It is advised to consume protein with every meal as protein intake flattens the glycemic response of food and helps minimize postprandial glucose excursions (Vishwanathan V., et al 2018). The Recommended Dietary Allowance (RDA) for pregnant women is an extra 9.5 g of protein per day in the second trimester and 22 g of protein per day in the third trimester, according to the ICMR-NIN 2020 guidelines (Nutrient Requirements for Indians. A report of the expert group ICMR NIN, 2020). The primary protein sources include milk and milk products, eggs, soya, pulses and lentils, lean meats (fish and chicken breast), nuts, and seeds.

This macronutrient is of further importance in the Indian context, where diets are predominantly carbohydrate-based and protein-deficient. Whole pulses are a source of both protein and dietary fiber. These can be added to cereals to improve the fiber and protein content of the meal. The quality of the protein is improved by altering the pulse : cereal ratio, which goes from 1:7 in the regular diet to roughly 1:5 and 1:3 in the second and third trimesters, respectively (Seshiah et al., 2020). There is a reduction in the rise of post-meal blood glucose levels, when the consumption of carbohydrates in preceded by the intake of protein and fiber (Shukla AP., et al 2015).

1.6.4 Fat Intake

IOM recommends that fat makes up 20-40% of the total energy intake. Saturated fats and trans fats should not exceed 10% of the total calorie intake. The remaining fat allowance is divided between Monounsaturated fatty acids (mustard oil, peanuts, nuts and seeds) with a minimum of 10-20 % of energy intake, and 5-10 % from Polyunsaturated fatty acids (soya bean oil, sunflower oil, corn oil). There are indications of the benefits of PUFA omega-3 oils (fish, fish oil, flax oil), the exact effect and quantity of which are yet to be established.

The minimum amount of fat should be 20% of energy, of which 30 g can be visible fat, according to the ICMR-NIN 2020 recommendations. Limiting the quantity of saturated fats (SFA), avoiding trans fats, and increasing the proportion of polyunsaturated and monounsaturated fats (MUFA) are all advised. SFA consumption should be lowered by using low-fat dairy products and lean meats like fish and chicken. Avoid foods high in fat, such as deep-fried foods, bakery goods, ready-to-eat packaged foods, and high-fat sweets, as they contain trans fats (Nutrient Requirements for Indians: A report of the expert group ICMR NIN, 2020).

Nuts rich in MUFA, protein, fiber, and antioxidants, such as walnuts, pistachios, and almonds, are also low in carbs. According to a study by Gulati S et al. (2016), substituting a snack heavy in carbohydrates and SFA with raw, unsalted almonds can assist T2DM patients' glycemic control. This strategy can also be employed in GDM management.

1.6.5 Vitamin and Mineral Intake

There is an additional need of vitamins and minerals, including folic acid, iron, calcium, and vitamin D to meet the increased requirements of both the mother and the fetus. It is recommended to take varied and balanced diet, along with adequate supplementation to ensure required intake.

1.7 Physical Activity

Regular physical activity has been shown to reduce insulin resistance in all adult females regardless of whether they are pregnant or not. Physical activity activates the skeletal muscle cells' surface glucose transporters, which enhances glucose uptake, thereby lowering insulin resistance.

The majority of guidelines recommend planned moderate physical activity of at least 30 minutes per day or 150 minutes weekly in women with GDM who do not have any medical or obstetric issues that limit physical activity (Rasmussen et al., 2020). Brisk walking or seated bicycling for 10 minutes after each meal is advised to achieve this target.

Pregnant women, with or without GDM, have reduced levels of physical activity, according to the South Indian WINGS Model of Care research. According to the study, a low-cost, culturally sensitive Model of Care can help women with GDM significantly increase their physical activity levels, thereby improving their glycemic control. (Anjana et al., 2016)

1.8 Nutrition Counselling

Pregnancy offers a prime window of opportunity for modifying behavior towards good diet and lifestyle choices. It is a teaching opportunity for women and their offspring. The level of preparedness for change at this time is high because feelings are heightened due to the perception of risk associated with GDM. The possibility of an improved outcome through lifestyle and dietary modifications, without the need for medicines, further increases their preparedness for change. Additionally, there is a noticeable improvement in one's motivation, self-worth, and readiness to pick up new skills. (Zakaria et al., 2023). Women who have GDM as well as their children are more prone to developing T2DM in the future and are also predisposed to obesity and insulin resistance. Therefore, counseling at this time can be used to implement a

healthy lifestyle and break the vicious cycle of metabolic disorders from generation to generation.

Despite the fact that MNT is the bedrock for managing GDM, an unacceptable level of compliance with nutrition recommendations is seen. Rather than providing practical, contextual, and health-promoting guidance, nutrition advice is often confusing, prescriptive, and challenging to understand. This is a significant factor that contributes to non-adherence. Many of the obstacles to improving dietary compliance are associated with care providers' lack of training in nutrition self-management and counseling abilities (Tang et al., 2022).

As stated previously, no particular diet or dietary program is superior to any other. Throughout all the trials that compared various dietary regimes, the factors that contributed to the success of MNT were greater levels of nutritional counseling and more frequent visits from dietitians. Consistent advise offered by a skilled dietician, personalization, and more regular consultations with a dietician are the most important enablers to improve adherence to dietary guidance.

2. Literature Review

Efficiently managing GDM during pregnancy is a matter of utmost concern due to its far-reaching implications for both maternal and fetal well-being. A study of current dietary intake and food habits of newly diagnosed GDM patients is critical to understand the dietary practices and design an effective nutrition plan. The study first evaluates the relation of Body Mass Index (BMI) as a predictive marker for GDM and assesses the role of BMI as a risk factor for GDM. It then focuses on the role of Medical Nutrition Therapy (MNT), which is formulated to address the individual dietary requirements of newly diagnosed GDM patients. The viability and efficacy of individualised dietary counselling is evaluated in achieving glycaemic control and gestational weight gain among GDM participants. The perinatal outcomes studied post MNT include birth weight, head circumference, length and the need of Neonatal Intensive Care Unit (NIUC) admission for more than 24 hours. Thus, this literature review provides an overview of the important aspects of GDM management, addressing all the objectives of the study. It evaluates the importance of dietary habits,

predictive factors like BMI, individualised dietary counselling, and its impact on maternal outcomes like glycemic control, optimal gestational weight gain as well as fetal outcomes. This collective body of research facilitates our understanding of effective strategies for managing GDM and promoting both maternal and fetal well-being.

Swain et al. (2017) proposed that diet is an important factor to consider for the management of GDM. Review of the intake and food habits of patients, newly diagnosed with GDM usually reveal discrepancies in their diet intake. It is likely that there is an increased intake of refined carbs and sugars, and a deficit of proteins as indicated by study of their food habits. This diet is also likely to increase the propensity for complications in patients with GDM as their blood sugar is already raised, and this diet may act as an impetus to complications.

One such prospective cohort study, “Maternal Antecedents of Adiposity and Studying the Transgenerational role of Hyperglycemia and Insulin” (MAASTHI), was conducted by Deepa et al. in 2020. They targeted 1,777 pregnant women in urban Bengaluru. They assessed the association between dietary practices and the incidence of GDM in Indian women as part of this research. They proved that 17.6% of the recorded subjects were suffering from GDM, of whom 76.7% were red meat eaters. Red meat consumption has been found to raise the risks of developing GDM even after adjusting variables such as socioeconomic status, age, and family history of diabetes. This study points towards a need for future investigations regarding increased red meat consumption during pregnancy.

A review study conducted by a group of authors, Chawla G.K. et al. (2023), showed that dietary behavior of pregnant women influences their nutritional status and recommended food intake in pregnancy. Excess weight gain in pregnancy can be avoided with a healthy diet and regular exercise.

A systematic review which covered 70 studies and included a notable cohort of women was done by Torloni et al. (2009). This study aimed to assess and quantify the risk of GDM based on pre-pregnancy maternal BMI. The results showed a linear relation between risk of GDM and pre-pregnancy BMI. Overweight and obese women faced significantly greater risk of developing GDM as compared to underweight women. The incidence of GDM increased by 0.92% for every 1 kg/m^2 increase in

BMI. These results emphasise the need for educating women of reproductive age to maintain a healthy weight before planning pregnancy.

According to Giannakou et al. (2019), GDM is a commonly seen complication of pregnancy. GDM has both short-term and long-term risks for maternal and fetal health. Various international bodies have different protocols for the screening, diagnosis, and treatment of GDM, but MNT is unanimously considered as the cornerstone of GDM management. MNT, physical activity and regular self-monitoring of blood glucose are the vital components in effectively managing Gestational Diabetes Mellitus. These lifestyle modifications can only be done by active participation and support provided by the family. The healthy dietary behaviour implemented during pregnancy can eventually influence the eating habits of an entire family.

Through a case-controlled study pattern, Singh & Urooj (2015) studied the effects of pre-pregnancy weight, dietary practices and lifestyle on gestational diabetes. The study was conducted with 102 pregnant females and their dietary practices, physical activity pattern, and anthropometric data was evaluated. Results highlighted that GDM patients had an increased BMI and unbalanced diet with a reduced protein intake. GDM subjects, also consumed higher carbohydrates and fats as compared to recommended balanced diet. Pregnant females did not engage much in physical activity. The study reinforces the need to maintain a healthy pre-pregnancy weight, balanced dietary intake, and regular physical activity for preventing GDM.

Yessoufou et al. (2015) underscored the role of BMI as an important predictive marker for GDM during pregnancy Several studies show the association of an increased risk of GDM with a high pre-pregnancy BMI. Women who start their pregnancies with a higher BMI are at a higher risk of developing hyperglycemia during pregnancy. This enables the identification of women who are at a higher risk of altered glucose metabolism during pregnancy. Women should be educated to achieve a healthy BMI through pre-conception nutrition intervention programmes to reduce the overall risk of GDM.

Bahl et al. (2022) conducted a population-based study on pregnant women in South Delhi. They examined the results to understand the prevalence of GDM, risk factors associated with GDM, and unfavorable pregnancy outcomes related to GDM. The

conclusion obtained was that about 19.2% of pregnant women in a low to medium socioeconomic area of South Delhi were diagnosed with GDM. The risk factors were found to be advanced maternal age, higher BMI values, and the presence of pre-diabetes at conception. Importantly, antenatal programs for nutritional interventions in overweight and obese pregnant women were highlighted as GDM preventive strategies.

The study carried out by Zugravu et al. (2023) aims to evaluate the effectiveness of distinct nutritional strategies for GDM prevention. Measures that were successful in decreasing the prevalence of GDM were done using moderate intensity interventions at an individual level by promoting motivation. Effective nutritional adjustments included the optimization of calorie consumption, portion control, as well as eating whole grains, vegetables, and fruits. At the same time, a reduction in the consumption of simple carbohydrates and highly processed foods is also advocated. This can assist in the implementation of solutions for GDM prevention during antenatal care.

Kapur et al. (2020) reviewed the role of MNT in GDM treatment. The review shows a lack of consensus among the various professional bodies about what constitutes an appropriate diet for women with GDM. Traditionally, this has been one of carbohydrate restriction. However, this has been questioned and a less restrictive diet with complex, low to medium glycaemic index carbohydrates is recommended. This recommendation also involves the liberal use of fruits and vegetables. Also, MNT should involve regular consultations with a dietitian.

Ravel et al. (2023) focused on adherence to Medical Nutrition Therapy among antenatal women having GDM in Puducherry, India. The study shows that almost two-thirds of these women were non-adherent to MNT. Unemployment, length of the gestational period, financial constraints, a lack of awareness regarding the necessity for MNT, and pressure from joint families were some of the major factors contributing to non-adherence.

Juan & Yang (2020) examined the “prevalence of GDM, risk factors, methods to prevent it, and lifestyle changes in the China region,” for an improved understanding of the latest epidemiology of GDM. It highlighted the importance of counselling before conception for all women of reproductive age. Women who have a history of GDM in a previous pregnancy or a family history of GDM face a higher risk and

should be given special attention. It was recommended that women of reproductive age who plan to conceive should attempt to normalize their blood sugar levels as much as possible prior to pregnancy. A multidisciplinary approach is suggested, which includes preventative management, vigorous health education efforts, early diagnosis, and multidisciplinary care to prevent and manage GDM in high-risk cases.

Nutritional intervention studies for GDM patients were reviewed by Helm et al. (2022). This review highlighted the gap in information between diabetes self-management education and Medical Nutrition Therapy. Findings show that, unlike studies related to Medical Nutrition Therapy, which are consistent, nutrition knowledge varied across different types of protocol for self-management of diabetes. The study recommended the initiation of nutrition treatment immediately after the diagnosis of GDM, for the benefit of both the woman and fetus. The study concluded that both the generalized and specialized approaches of nutrition education can reduce hyperglycemia and its large negative impacts in women with GDM.

Motahari-Tabari et al. (2023) examined counselling, which was based on the Information-Motivation-Behavioral skills model. It was designed to establish the effectiveness of the model in preventing GDM among obese women or those who gain excess weight during pregnancy. The theoretical framework of IMB is frequently applied to initiatives for health intervention and health change. The medical reports of these subjects demonstrated that this model had a considerable effect on their ability to maintain a healthy weight consistently. The study also showed how this intervention led to a lower rate of gestational diabetes.

Su et al. (2023) published research about the perceptions of the patient group with newly diagnosed Gestational Diabetes Mellitus regarding their medical condition. The patients were concerned about their safety and the well-being of their offspring despite the fact that they had difficulty in changing their perceptions concerning their health. The participants struggled with forming well-informed dietary choices, as well as changing their lifestyles. This study showed how the patient group benefited from the individualized support approach regarding their ability to understand and manage the disease in a effective way. It should be noted that while considering how women can manage GDM, health practitioners should also work on easy-to-follow self-management protocols.

Zhang & Ning (2011) observed that the prevalence of GDM impacts 10% of all pregnant women worldwide. Another observation was the importance of personalised treatment approaches, via management through lifestyle modifications. The study took place in the Thai Binh Province between June 2021 and May 2022. The study evaluated the impact of lifestyle changes on the patient's ability to regulate blood sugar levels. Among 1035 participants, 20.2% had GDM. After a two-week lifestyle intervention, 82.6% of GDM patients achieved successful glycaemic control. Factors influencing control included: age, pre-pregnancy BMI, and the number of diagnostic criteria met.

Miao et al. (2017) examined pregnancy outcomes of GDM and its relation with maternal BMI and gestational weight gain. It observed 832 pregnancies complicated with GDM. A high pre-pregnancy BMI and excessive GWG were found to be associated with higher incidence rates of Large for Gestational Age newborns and an increased chance of unfavorable outcomes such as cesarean section and macrosomia.

By early screening and treating pregnant women with GDM, Oskovi-Kaplan & Ozgu-Erdinc (2021) observed the possibility of decreasing the threat of fetal macrosomia and the associated increased risk of fetal morbidity, death, and delivery difficulties. They found that lifestyle modifications like a balanced diet and physical activity reduce insulin resistance (IR), fasting and postprandial glucose levels, and may reduce the need for insulin therapy. Pregnant women with GDM should perform moderate-intensity exercise for 30 minutes, five days a week, or at least 150 minutes per week, unless there is a medical or obstetrical contraindication.

Alejandro et al. (2020) researched GDM's effects on long term maternal and fetal outcomes, as well as health hazards that could potentially affect future generations. Their work was centered on using preclinical models in understanding the basic pathophysiology of GDM. The authors also advocated for a need to improve scientific knowledge and processes of diagnosis in the prevention and early management of GDM to counter its effects. The work showed that GDM prevention is vital in interrupting the vicious cycle of obesity and T2DM formed as a result of GDM.

The study by Papazian et al. (2017) analyzed the impact of maternal BMI and GWG on neonatal outcomes. The authors conducted a retrospective, cross-sectional observational study of 1000 full-term births in Lebanon. Primary variables that were

considered were maternal factors like age, BMI, and GWG, and newborn weight, height, head circumference, and Apgar score. Women with GWG below or over IOM limits showed significant rates of adverse outcomes, such as macrosomia and lean body weight for neonates. Apgar score, birth height, or head circumference were not impacted by mothers' BMI and GWG.

3. Research Gap

A comprehensive literature evaluation on the themes of GDM concerning prevalence, diagnosis criteria, treatment modalities, and GDM care was carried out. The review covered a wide variety of topics in the related context. Several investigations demonstrated various diagnostic criteria and a lack of consensus among different professional groups. According to these studies, Medical Nutrition Therapy is the backbone for the management of GDM. Various dietary approaches are used globally, but in the context of India, it is essentially a carbohydrate-controlled plan along with adequate protein, fibre, and healthy fat. Regardless of the dietary protocol used, it was shown that for MNT to be effective, pregnant women needed brief instructions tailored to their individual needs, reinforcement to follow nutrition advice, and self-monitoring of blood glucose.

It has significant long-term effects since women with GDM are more likely to develop T2DM later in life, and their offspring are predisposed to metabolic disorders. It requires a collaborative approach between doctors and dieticians to use this opportunity to impart nutrition education as a strategy to manage GDM, which is cost-effective and controls anxiety in the antenatal period caused by medicine/insulin intervention. This is a window of opportunity which can be used to increase awareness, to break myths, and to instil healthy eating practices for the entire family. Since India is a developing country with low resource settings, implementation and compliance are additional challenges. This research study focused on developing individualized nutritional plans along with a comprehensive evaluation of the effectiveness of those plans. There is a need to develop easy-to-understand and practical modules that can effectively impart MNT in the Indian healthcare structure. The effects of MNT on Gestational Weight Gain and neonatal outcomes require further elucidation. Newer technological advancements like Continuous Glucose

Monitoring (CGM) and their potential use in MNT must also be studied. The possible use of supplements like probiotics and myo-inositol in managing GDM may be another area of interest for future work.

4. Problem Statement

GDM poses a short-term and long-term health risk to both the mother and the child. Mothers with GDM have a significantly higher incidence rate of developing T2DM in later life. Children of GDM pregnancies are predisposed to metabolic disorders and obesity. Thus, GDM contributes to the obesity and T2DM epidemics in our country. Since GDM impacts both the current and the future health of multiple generations, GDM management should be a public health priority.

Managing GDM, like managing T2DM, centres on maintaining normal glycaemic levels of the mother. Diet directly affects blood sugar levels. Therefore, Medical Nutrition Therapy should always be the first-line treatment for GDM. MNT can regulate blood glucose levels, gestational weight gain, and consequently fetal growth. However, despite patient reluctance to move towards medicine/insulin intervention, patient compliance with MNT remains low. The primary reason is an endemic lack of individualized counselling and the widespread use of ‘one size fits all’ prescriptive advice. Other confounding factors include cultural myths about food and a general lack of awareness regarding the nature of GDM.

For MNT to be an effective recourse for GDM, a collaborative effort between a qualified dietitian and the patient is required. An initial assessment is done by a qualified dietitian to get anthropometric data like height, weight, and BMI. A one-on-one session is done to learn about food habits, cultural preferences, family support systems, and the learning capabilities of the patient. After analysing the current nutrient intake, an individualized diet plan is designed in accordance with the principles of MNT. In order to facilitate patient compliance, special care is taken to make sure that the plan is practical and easy to understand. Follow-ups at regular intervals are crucial so that the diet plan can be modified and adjusted on the basis of patient feedback, glycemic control, and the desired gestational weight gain.

The current study is done on a smaller sample set, but the results will demonstrate the effectiveness of MNT as a treatment modality for GDM. This will give insights for better application of MNT for GDM management. In the future, research with larger sample sets or studies done in hospital settings will also yield helpful data. Any such data will help combat the rapidly increasing rate of GDM, safeguard the health of future generations, and decrease the load on public health infrastructure. Although the role of BMI as a predictor of GDM has been researched, there is room to further examine the importance of prenatal weight management in GDM prevention.

5. Research Objectives

Aim

To study the effectiveness of individualized Medical Nutrition Therapy in managing Gestational Diabetes Mellitus in terms of glycemic control, gestational weight gain, and fetal outcome.

Objectives

1. To assess the dietary intake and food habits of women with newly diagnosed Gestational Diabetes Mellitus.
2. To study the relation between Body Mass Index and incidence of Gestational Diabetes Mellitus.
3. To study the effect of individualized Medical Nutrition Therapy on glycaemic control and gestational weight gain.
4. To evaluate the neonatal outcomes in terms of birth weight, gestational age, length, and head circumference.

6. Research Methodology

Study Area: The present study will be done in a private clinic setting with patients from various hospitals located in Delhi.

Study Design: Experimental study.

Study Period: 3-4 months.

Study Population: The analysis will include 90 antenatal women having a diagnosis of GDM referred by a gynaecologist for Medical Nutrition Therapy. The study will adopt a purposive sampling technique. The geographical area surrounding Delhi is selected because of the high incidence of disease in urban Delhi.

Sample Size Calculation: Using G*Power Version 3.1.9.7, with parameters as follows: effect size 0.3, α (error) 0.05, and power 0.80, the sample size came out to be 71. Therefore, the minimum sample size required is 71. (Faul et al 2007, Faul et al. 2009)

Taking 20% as the non-response rate:

20*71/100 = 14.2 ~ 15

Therefore, the corrected sample size is:

71+15 = 86 ~ 90

Inclusion Criteria

i. Age between 18 and 45 years
ii. Singleton pregnancy with GDM diagnosed between 24 and 28 weeks

Exclusion Criteria

i. Women having a prior history of diabetes mellitus.
ii. Multiple pregnancy
iii. Pregnancy with Assisted Reproductive Technology
iv. Those having any comorbidities like cardiac or renal disease.

Method for Study

Within the ambit of this investigation, an integrated methodology will be adopted. To collect the necessary information for the study, a combination of qualitative and quantitative research methods will be utilized. This will include the use of a questionnaire and a personalized informative interview with open-ended questions. Qualitative research will include personal one-to-one interview sessions with each GDM subject.

The study will include 90 antenatal women having a diagnosis of GDM referred by a gynaecologist for Medical Nutrition Therapy.

Step 1 (Day 1)

Assessment: Initially, informed consent will be taken from the patient. The relevant anthropometric and antenatal data, including weight and height, will be collected. This will be followed by the calculation of BMI. The energy requirements will be calculated according to the BMI category (IOM, 2009). An assessment of current dietary intake and food habits will be done, along with portion sizes of each food consumed. This data will be collected through the medium of an interviewer-administered dietary habit questionnaire and a three-day dietary recall (two weekdays and one weekend).

Counseling: This data will be used to evaluate healthful eating practices and detect harmful ones. Specifically, sources of carbohydrates and sugar, along with their portion sizes and their frequency, will be studied. The information gathered will be used to motivate the subject to change unhealthy eating practices while praising the positive aspects. Patient will be encouraged to participate in designing a balanced meal-plan to ensure compliance and adherence. Special attention will be given to explaining the type and amount of carbohydrates to be used in each meal. The benefits of adding protein to each meal will be highlighted. A T-shaped plate model (Kapur et al 2021) will be used to depict a healthy Eating Plate.

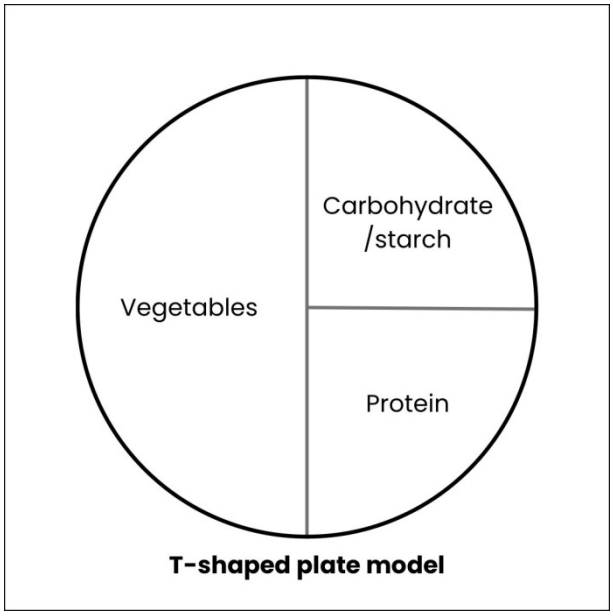

Figure 4: T-shaped plate model (Kapur et al 2021)

A Healthy Eating Plate model, self-monitoring of blood glucose (SMBG) and its charting, and a food journal will be used to support sustained behavior change.

Step 2 (Day 7-10)

A personal interaction with the patient will be done to assess coping behavior, review SMBG data, and make any dietary changes required for better glycemic control and compliance.

Step 3 (Day 15 - Delivery)

Women who respond to MNT will continue with the therapy, and those requiring pharmacological intervention will be referred back to the gynaecologist.

For women on MNT, weekly follow-ups are conducted till delivery, via telephone or WhatsApp, to monitor recorded blood sugar levels and answer any queries or doubts.

All the relevant data will be collected, including gestational age at the time of diagnosis, gestational age at the time of delivery, maternal weight at the time of diagnosis of GDM, maternal weight at the time of delivery, and the mode of delivery. Gestational weight gain will be computed as: [weight at the time of delivery – weight at the time of diagnosis of GDM]. According to the IOM 2009 recommendation, the GWG category will be calculated as [gestational age at delivery – gestational age at the time of diagnosis of GDM] x [Weight gain per week in $2^{nd}/3^{rd}$ trimester (kg/week) according to their BMI category].

Neonatal outcomes in terms of birth weight, length, and head circumference will be recorded. The following will be calculated: macrosomia (greater than 4000 gm), preterm delivery (less than 37 weeks), small for gestational age (SGA, defined as birth weight less than 10th percentile), appropriate for gestational age (AGA, defined as birth weight between 10th and 90th percentile) and large for gestational age (LGA, defined as greater than 90th percentile).

The Intergrowth 21 chart will be used to calculate birth weight according to gestational age.

Step 4

Data is to be collected using a structured proforma. The data will be entered into an MS Excel Sheet and then statistically analysed using SSPS 16.0 (IBM Corp., Armonk, NY). Continuous variables will be given as means ± standard deviations or median values. Categorical variables will be presented as percentages. Comparisons

for continuous data will be performed using a Student t-test or one-way ANOVA. Categorical variables will be compared using the chi-square test or Fisher test.

7. Expected Outcomes

This study will provide insight into the food habits of newly diagnosed GDM patients in Urban Delhi. Further, it will examine the relation of food habits and nutrient intake with the prevalence of GDM. The study will determine the effectiveness of personalised, well-structured, and easy-to-follow diet plans in increasing patient compliance and improving glycemic control. Regular follow-ups with the subjects, till delivery, will determine the efficacy of MNT without the need for pharmacological intervention in achieving glycemic control. This approach is expected to yield positive outcomes. The study will also highlight the relationship between gestational weight gain and neonatal birth weight. Other neonatal parameters like length and head circumference will also be studied. Since babies who are large for gestational age have a higher risk of developing metabolic disorders like obesity and T2DM in the future, this data is significant. Excessive weight gain during pregnancy leads to higher retention of weight after delivery. This increases the risk of obesity and GDM in subsequent pregnancies. Therefore, medical professionals must adopt practical measures to monitor and stop excessive gestational weight gain. The role of increased BMI as a risk factor and predictor for GDM is another anticipated result. This knowledge may be used during pre-conception care to control the mother's BMI and prevent complications such as GDM. This research will highlight the significance of individualised dietary counselling as a cost-effective, first-line treatment for the management of GDM, thereby reducing the need for medicine and insulin therapy. Women with GDM and their offspring are an easily identifiable population vulnerable to T2DM and other metabolic disorders. This presents a perfect window of opportunity to educate women with GDM about healthy eating practices, thus preventing a vicious generational cycle of diabetes and obesity epidemic.

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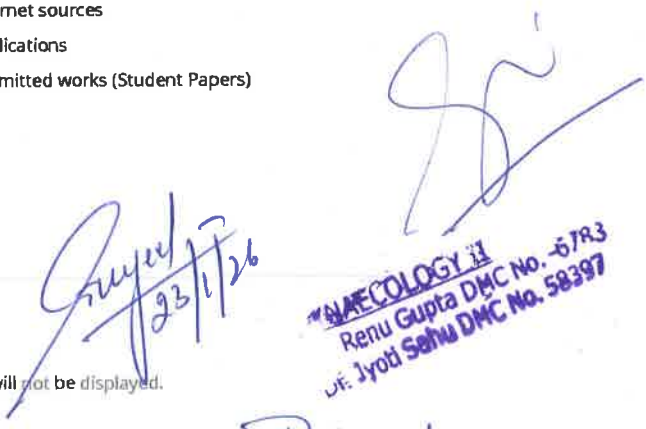

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